

# **FINAL REPORT**

## **AUDIT DESCRIPTION**

Audit Type: Extramural Technical Systems Audit

Date Review Performed: 7 October 2009

Auditor: Mr. Michael Ray, National Health and Environmental Effects Research Laboratory (NHEERL), U.S. Environmental Protection Agency

QPCR Technical Consultant: Dr. Rich Haugland, National Exposure Research Laboratory (NERL), U.S. Environmental Protection Agency

Project Audited: BEACHES Study: QPCR Water Sample Analysis by EMSL Analytical, Inc.

NHEERL Principal Investigator: Dr. Timothy Wade

Review Location: EMSL Analytical, Inc. Facility, Westmont, NJ

Date: 10 November 2009

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## 1.0 BACKGROUND

### 1.1 OBJECTIVE

A technical systems audit (TSA) was performed October 7, 2009 on BEACHES Study: QPCR Water Analysis by EMSL Analytical, Inc.” The NHEERL Principal Investigator for the BEACHES Study is Dr. Timothy Wade. The TSA was conducted in the EMSL Analytical, Inc facility in Westmont, New Jersey.

The primary objective of this TSA was to provide assistance to the investigator and the study staff to help ensure that the study quality assurance (QA) and quality control (QC) procedures are appropriate for the anticipated end use of the data and that the study documentation is adequate to ensure the defensibility of the study results.

### 1.2 APPROACH

The following approach was used in conducting this TSA:

- (1) Preliminary review of study documentation consisting of the following:

Work Plan for Work Assignment 0-01 Westat Contract EPD-09-040 NEEAR Water Study for Beaches Program

Statement of Work for Work Assignment 0-03 Westat Contract EPD-09-040 NEEAR Water Study for Beaches Program

- (2) Preparation of a checklist based on information in the documentation listed in the items above, to be used as a guide for conducting the TSA (see Appendix A).
- (3) Conduct of the TSA according to the following schedule:

October 7, 2009

Introductory meeting with key staff at the laboratory

Tour of the laboratory

Observation of lab staff performing QPCR analyses of filter samples

Interviews with key staff to review procedures and records and to complete the TSA checklist

Exit briefing with key staff

### 1.3 REVIEW PARTICIPANTS

#### 1.3.1 Reviewers

Members of the TSA review team were Mr. Michael Ray (Environmental Public Health Division Quality Assurance Manager) and Dr. Rich Haugland, U.S. Environmental Protection Agency (EPA).

#### 1.3.2 Project Personnel

The project personnel included Dr. Timothy Wade (NHEERL BEACHES Study PI), Mr. Kurt Patrizi and Ms. Amy Kominski of Westat, Inc., and the following EMSL Analytical, Inc. personnel: Mr. Robert DeMalo (Senior Vice President, Laboratory Services), Mr. Charles La Cerra (Special Projects Manager), Dr. Quanyi "Charlie" Li (PCR Laboratory Director), and Ms. Diane Miskowski (Business Development Manager).

## 2.0 SUMMARY

The staff is well-qualified in all phases of the study. Frequent communications have enhanced the staff's effectiveness and the overall quality of this study by providing the opportunity for regular peer involvement in reviewing progress, addressing

problems, and planning changes.

The laboratories are well-maintained and are adequate to produce results of a quality sufficient to meet the objectives of this study. However, it would be desirable to have more lab space.

In completing the checklist and from the limited review of study records, there were areas that were identified as exemplary. Those findings are documented in Section 3.0. Areas where there was room for improvement is documented in Section 4.0.

It is the reviewers' intent that the findings and recommendations in this report increase the study personnel's awareness of QA and QC activities and good research practices and assist them in making changes to improve the quality of the research activities and study documentation, and to enhance the verifiability and defensibility of the study results.

### 3.0 EXEMPLARY FINDINGS

1. Laboratory notebooks – Lab notebooks kept by the staff were neat and easy to follow. Templates were used for calculations and the experiments were printed out and taped into the books in a chronological order.
2. Technical Skills of Staff – All technical staff members were knowledgeable and clearly competent for their project tasks. Dr. Li received QPCR training for the BEACHES water samples from Dr. Haugland prior to commencement of sample analysis. Dr. Li demonstrated his skills to Dr. Haugland during the audit by performing the operating procedure for QPCR analysis.
3. Good communication was demonstrated between EMSL lab staff and Westat and EPA field personnel.
4. EMSL has a dedicated QA staff who follow a specific checklist and operating procedure for reviewing QPCR analytical data. Also, the EMSL QA Manual has a separate module for environmental microbiology analysis.

#### 4.0 RECOMMENDED IMPROVEMENTS

1. Observation: Due to space limitations, the DNA free hood is located in the same room where other QPCR analysis procedures are performed. Also the hood does not have laminar airflow.

Discussion: EMSL personnel perform surface swipe tests and monitor the lab air to check for possible contamination. However these checks are time consuming and contamination could still occur. Therefore, the planned move to EMSL's new facility which will have laminar flow hoods and separate rooms for QPCR activities should be expedited.

2. Observation: EMSL does not retain copies of the signed cover sheets for the data reports that it sends to Westat.

Discussion: The signed cover sheets are needed to verify that all required reviews of the data reports have been performed. Although EMSL should be able to obtain signed cover sheets from Westat, it would be more timely and efficient to retain copies in their files in case they are needed by EMSL to document their reviews.

**APPENDIX A**

**COMPLETED**

**TECHNICAL SYSTEMS AUDIT CHECKLIST**



## TECHNICAL SYSTEMS AUDIT CHECKLIST

Title: **National Epidemiologic and Environmental Assessment of Recreational Water – EMSL Analytical, Inc.**

Review Date: October 7, 2009

Location(s): EMSL Facility, Westmont, NJ

NHEERL Principal Investigator: Tim Wade, NHEERL/EPHD

Reviewers and Affiliations: Mike Ray, NHEERL

Project Personnel Present: Kurt Patrizi, Amy Kominski, Robert DeMalo, Charles La Cerra, Charlie Li, Diane Miskowski

Completed by: Mike Ray

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
A. Planning Documents				
1. Is there a written and approved protocol, research plan, or work plan for this study?	X			The work plan serves as the QAPP.
2. Is there a written and approved Quality Assurance Project Plan (QAPP) or QA narrative Statement for this study? If not, briefly describe how/where QA & QC requirements and procedures for the study are documented.	X			See A.1. above.
3. Are written and approved OPs used in this study? If not, briefly describe how/where study procedures are documented.	X			The QPCR procedure was provided by EPA.
4. Are standard forms used in this study? If yes, are they available to all anticipated users?	X			

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
5. Is the actual study design and conduct as specified in the study planning documentation (e.g., OPs, protocols, work plans, QAPPs)? If not: → Are changes/deviations clearly documented?	X			
<b>B. Quality Objectives and Performance Criteria</b>				
1. Is the anticipated use of the data known and documented?	X			Stated in the QAPP
2. Have study quality objectives, consistent with anticipated data use, been established and documented?	X			Stated in the QAPP.
3. Have performance criteria for measurement data (e.g., detection limits, precision, bias) been established and documented?	X			Stated in the QAPP and operating procedures.
4. Are there established procedures for assessing whether quality objectives and measurement data criteria have been met? If yes, briefly describe.	X			QA staff use a specific checklist and an operating procedure to review QPCR data.
5. Are there established procedures for corrective or response actions when measurement performance criteria or other quality objectives are not met? If yes, describe.	X			Analyses are repeated when QC criteria not met.
6. Are items 1-5 above consistent with study planning documentation (e.g., OPs, protocols, work plans, QAPPs)? If not, are changes/deviations clearly documented?	X			

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
C. Study Organization and Personnel				
1. Are all key study participants, roles, and responsibilities specified in study planning documentation?	X			
2. Are all study personnel specified in study planning documentation?	X			
3. Is the fulfillment of these requirements documented for applicable personnel?	X			<ul style="list-style-type: none"><li>Training for the contractor on the highly specialized scientific PCR equipment was provided by USEPA.</li></ul>
D. Facilities, Equipment, and Supplies				
1. List any key facilities and briefly describe the major activities performed in support of the study. Indicate whether each facility is adequate. If not, briefly describe areas where improvements may be desirable or necessary.				The QPCR lab space is well-maintained and adequate to produce quality data. However, it would be desirable to have more lab space and to employ laminar airflow hoods.

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
<p>2. List below key equipment used in the study. For each item, indicate whether testing, inspections, and maintenance are conducted regularly. If yes, specify:</p> <p>→ if acceptance testing, calibration, or inspection is done</p> <p>→ frequency and range of calibration and calibration checks and the types of calibration standards used</p> <p>→ person or organization responsible for performing calibration checks, inspections, and maintenance</p> <p>→ if procedures are documented in an operating procedure</p> <p>→ if a calibration or maintenance log is kept</p> <p>→ if the same piece of equipment is used for each procedure (e.g., same sterile hood for culture)</p>	X			<ul style="list-style-type: none"> <li>Cell suspensions of the calibrator strains, <i>Enterococcus faecalis</i>, American Type Culture Collection (ATCC) 29212, <i>Bacteroides fragilis</i> ATCC 25285, and reference strain, <i>Geotrichum candidum</i>, University of Alberta Microfungus Collection and Herbarium (UAMH) 7836, were provided to the contractor by the USEPA. The cell suspensions provided are stored at - 70° C, until used. Preliminary QPCR analyses were performed using four tubes of these suspensions prior to the start of the study, and the results (C<sub>T</sub> values and run files) were reported to USEPA. Subsequent average results for these samples on each day of analysis were checked to determine if they were within + 2 C<sub>T</sub> units of the average of the initial values.</li> <li>The contractor monitors the performance of the thermal cycling instrument and PCR reagents based on ongoing calibrator sample analysis results. (See above.) In the event of failure to meet these performance criteria, the contractor prepares and analyzes a new set of calibrator extracts, identifies the source of the problem (e.g., reagents or instrument), and takes corrective action.</li> </ul>

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
3. Is acceptance inspection or testing performed on any supplies/reagents/medias used in this study? If yes, briefly describe inspection or testing procedures and associated acceptance criteria.	X			Disposable aerosol barrier pipette tips are used for all liquid transfers. Tubes and other disposables that are not sterilized by the manufacturer are autoclaved before use. <u>All supplies and disposables are DNA-free.</u> DNA free water is purchased from a vendor.
4. Are acceptance testing, inspection, maintenance, and calibration procedures performed as specified in study planning documentation? If not, are changes/deviations clearly documented?	X			
<b>E. Laboratory Measurements</b>				
1. Are calibration methods available for each of the following? If so, are they clearly linked to the laboratory measurements? If not, what steps have been taken to ensure accuracy and precision of measurements?  → QPCR assays	X			
2. Are the calibration ranges appropriate for the measurements taken above?	X			
3. Do published standards or ranges exist for the measurements above, and are they applicable to the study?				
4. Are control samples run? If yes, briefly describe.	X			See D.2 above.

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
5. Are other routine QC checks performed? If yes, briefly describe.				<ul style="list-style-type: none"> <li>All pipettors are calibrated by a vendor prior to commencing work and on a semiannual basis afterwards.</li> </ul>
6. Are data transformations/calculations and units clearly documented?	X			
7. Are the dates of measurements documented?	X			
8. Are the persons who performed the measurements clearly defined?	X			
9. Are items 1-8 above performed as specified in study planning documentation? If not, are changes/deviations clearly documented?	X			
<b>F. Filter Samples</b>				
1. Are there written and approved procedures for lab personnel to follow when receiving, storing, and analyzing samples? If yes, note whether they have been distributed to all appropriate personnel participating in the study. If not, list how/where these procedures are documented.	X			The contractor maintains a dedicated sample data base that is used to record all sample IDs as samples are checked into the laboratory. The contractor checks each batch of samples received to determine that all expected samples are present.
2. Do the samples require special packaging and/or storage conditions? If yes, describe the conditions and any documentation that these conditions were maintained from sample collection through analysis and archiving.	X			The filter samples are shipped to the lab overnight on dry ice. All samples are stored in a -70 degrees C freezer at the lab until they are analyzed. Refrigerator and freezer temperatures are recorded each weekday morning and afternoon.
<b>G. Quality Assessments</b>				

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
<p>1. Have any of the following external or self-assessments been conducted or planned for the components of this study (e.g., support facilities, data management procedures)? If yes, briefly describe.</p> <p>→ peer review</p> <p>→ surveillance/site visit</p> <p>→ technical systems audit</p> <p>→ performance evaluation</p> <p>→ data quality assessment</p>	X			<p>A readiness review was performed prior to actual sample analysis.</p> <p>The contractor analyzed <u>performance evaluation samples</u> during the study.</p> <p>The NHEERL BEACHES Study PI performed a site visit.</p> <p>This review is considered a TSA.</p> <p>Performance evaluations are performed on an annual basis for the basic laboratory equipment.</p>
2. Are these assessments conducted or planned as specified in the study planning documentation? If not, are changes/deviations clearly documented?	X			
<b>H. Record Keeping and Data Management</b>				
1. Is there an index list of all data, records, samples, and specimens to be maintained in this study?	X			

REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
2. Are all study records (e.g., floppy disks, log books, notebooks, instrument outputs, samples/specimens, correspondence) clearly cross-referenced (e.g., by protocol #, date, experiment)?	X			
3. Is there an individual responsible for compiling all study data and reporting to the principal investigator?	X			Charlie Li compiles the data and has it sent to Westat for subsequent submission to the NHEERL PI.
4. Are study records maintained in a central file?	X			There is an electronic file on Charlie Li's computer and hardcopy reports are maintained in Charlie Li's file cabinet. The electronic file is backed up daily.
5. Are hand-written records recorded in numbered or otherwise uniquely identified notebooks or binders which are assigned to individual staff members?	X			
6. Are the initials of each person using a notebook or binder listed in the front?	X			
7. Is dark, permanent ink used and are corrections made with a strikeover and initialed? Is the reason for the change given?	X			



REVIEW QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
8. Are there procedures for routine verification of all data collection and management techniques? If yes, briefly describe and note whether verifications are documented in study records.	X			EMSL QA staff inspect forms to see that all appropriate data fields have values entered, and that entries are legible and reasonable. The staff documents their review by entering their initials on the field data sheets in provided spaces.
9. Are data reduction and analysis procedures clearly documented?	X			
10. Have data reduction and analysis procedures been validated? If yes, briefly describe. Is this documented?	X			An EPA operating procedure is used.
11. Are all data files and samples named according to a standard naming convention? If yes, briefly describe.	X			Data files are labeled "2009-Westat/EPA Beach Study"
12. Are all data records identified with a test/sample ID # and a protocol or study #?	X			
13. Are floppy disks, logbooks, and notebooks identified with the study/protocol #?	X			
14. Are items 1-13 above as specified in the study planning documentation? If not, are changes/deviations clearly documented?	X			